# CORRECTED VERSION

## (19) World Intellectual Property Organization

International Bureau



# 

(43) International Publication Date 24 June 2004 (24.06.2004)

PCT

### (10) International Publication Number WO 2004/052345 A1

- (51) International Patent Classification7: A61K 9/58, 9/62
- (21) International Application Number:

PCT/IB2003/005877

(22) International Filing Date:

11 December 2003 (11.12.2003)

(25) Filing Language:

English

(26) Publication Language:

English

(30) Priority Data:

1240/DEL/2002

11 December 2002 (11.12.2002)

- (71) Applicant (for all designated States except US): RAN-BAXY LABORATORIES LIMITED [IN/IN]; 19, Nehru Place, 110019 New Delhi, Delhi (IN).
- (72) Inventors; and
- (75) Inventors/Applicants (for US only): GANDHI, Rajesh [IN/IN]; c/o Sri K.C. Gandhi, Near Old Bus Stand, Banda, Dist. Sagar, 470334 Madhya Pradesh (IN). ISSA, Chayapathy [IN/IN]; House No. 14-82, Vemana Street, CTM Road, Madanapalle, 517325 Andhra Pradesh (IN). MA-LIK, Rajiv [IN/AT]; Haus 13/4, Unterer Schreiberweg, A-1190 Wien (AT).
- Common Representative: RANBAXY LABORATO-RIES LIMITED; c/o DESHMUKH, Jay, R., 600 College Road East, Suite 2100, Princeton, NJ 08540 (US).

- (81) Designated States (national): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.
- (84) Designated States (regional): ARIPO patent (BW, GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PT, RO, SE, SI, SK, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

### Published:

- with international search report
- (48) Date of publication of this corrected version:

26 August 2004

(15) Information about Correction:

see PCT Gazette No. 35/2004 of 26 August 2004, Section II

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: COATING COMPOSITION FOR TASTE MASKING COATING AND METHODS FOR THEIR APPLICATION AND USE

(57) Abstract: The present invention relates to coating compositions for taste masking and methods for applying the coating compositions to dosage forms to mask the taste of a medicinal substance. The taste masking coating compositions generally include a copolymer of acrylate and methacrylate with a quaternary ammonium group in combination with sodium carboxymethylcellulose and a polyvinyl alcohol-polyethylene glycol copolymer.



A (1)	ACC	EICATION OF	CIID IECT	BAATTED	
M. UL	MODI	FICATION OF A61K9	SOBOLCI	WAIIEN	_
TOO	7	161VA	/EO	A61K	$\alpha / c \alpha$
I PL	,	ADIKY	/ DK	ADIK	ひ/わン
71 V	•	7.00 2.110	, 00	UO TIV	91 UL

According to International Patent Classification (IPC) or to both national classification and IPC

### **B. FIELDS SEARCHED**

 $\begin{array}{ll} \mbox{Minimum documentation searched (classification system followed by classification symbols)} \\ \mbox{IPC 7} & \mbox{A61K} \end{array}$ 

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal, WPI Data, PAJ, BIOSIS

C. DOCUM	ENTS CONSIDERED TO BE RELEVANT	
Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
P,X	WO 03/026615 A (THOMAS MARTIN; LI SHUN-POR (US); LEE DER-YANG (US); MCNEIL PPC INC (U) 3 April 2003 (2003-04-03) paragraph '0098! - paragraph '0100! paragraph '0131! - paragraph '0133! paragraph '0138!	1-62
Υ	BASF CORPORATION: "Specification 'Kollicoat IR', Product Number 55554797" BASF CORPORATION, 'Online! 2001, XP002276164 NJ, USA Retrieved from the Internet: URL:http://www.basf.com/pharma> 'retrieved on 2004-03-30! the whole document  -/	1-62

χ Patent family members are listed in annex.
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention  "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone  "Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.  "&" document member of the same patent family
Date of mailing of the international search report 23/04/2004
Authorized officer  Giménez Miralles, J

		PCT/1B 03/058/7	
.(Continu ategory °	ation) DOCUMENTS CONSIDERED TO BE RELEVANT  Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.	
,	PACHIONE R.: "FCE Pharma. Lancamentos desafiam cambio volatil" REVISTA QUIMICA E DERIVADOS, 'Online! no. 408, September 2002 (2002-09), XP002276165 SAO PAULO, BRASIL Retrieved from the Internet: URL:http://www.quimica.com.br/revista/qd40 8/fcel.htm> 'retrieved on 2004-04-05! See last paragraph the whole document	1-62	
	US 6 136 347 A (BUECHELER MANFRED ET AL) 24 October 2000 (2000-10-24) cited in the application column 4, line 55 - column 5, line 21 column 5, line 28 - column 6, line 6 examples	1-62	
<b>Y</b>	US 6 106 861 A (DEMICHELIS ALAIN GILLES ET AL) 22 August 2000 (2000-08-22) cited in the application column 2, line 66 - column 3, line 25 examples	1-62	

PCT/IB 03/05877

Box I	Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)
This Inte	ernational Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:
1. X	Claims Nos.: because they relate to subject matter not required to be searched by this Authority, namely:
	Although claim 62 is directed to a method of treatment of the human/animal body, the search has been carried out and based on the alleged effects of the compound/composition.
2.	Claims Nos.: because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
з. 🗌	Claims Nos.: because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).
Box II	Observations where unity of invention is lacking (Continuation of item 2 of first sheet)
This Inte	ernational Searching Authority found multiple inventions in this international application, as follows:
1.	As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2.	As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3.	As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4.	No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:
Remark	on Protest The additional search fees were accompanied by the applicant's protest.
	No protest accompanied the payment of additional search fees.



PCT/IB 03/05877

		·	PC1/1B	03/05877
Patent document cited in search report	Publication date		Patent family member(s)	Publication date
WO 03026615 A	03-04-2003	US	2003068367 A1	10-04-2003
		US	2003072799 A1	17-04-2003
		US	2003086973 A1	08-05-2003
		US	2003070903 A1	17-04-2003
		บร	2003124183 A1	03-07-2003
		BR	0206061 A	13-01-2004
		BR	0206062 A	13-01-2004
		BR	0206086 A	23-12-2003
		CA	2446759 A1	03-04-2003
		CA	2446760 A1	03-04-2003
		CA	2447984 A1	03-04-2003
		NO	20032362 A	14-07-2003
		NO	20032363 A	23-07-2003
		NO	20032364 A	25-07-2003
		MO	03028990 A1	10-04-2003
		WO	03026624 A1	03-04-2003
		MO	03026625 A1	03-04-2003
		MO	03026626 A2	03-04-2003
		MO	03026628 A2	03-04-2003
		MO	03026612 A2	03-04-2003
		MO MO	03026613 A1	03-04-2003
		WO	03026614 A1	03-04-2003
		WO	03026615 A2 03026629 A2	03-04-2003
		WO	03026630 A1	03-04-2003
•		WO	03026627 A1	03-04-2003 03-04-2003
•		WO	03026616 A1	03-04-2003
		บร	2003219484 A1	27 <b>-</b> 11-2003
		US	2003232082 A1	18-12-2003
•		· US	2003232083 A1	18-12-2003
		US	2004018327 A1	29-01-2004
		ÜŠ	2003235616 A1	25-12-2003
		WO	03028618 A2	10-04-2003
		US	2003228368 A1	11-12-2003
		US	2003229158 A1	11-12-2003
		WO	03028619 A2	10-04-2003
		WO	03028989 A1	10-04-2003
		US	2003217908 A1	27-11-2003
		WO	03028620 A1	10-04-2003
US 6136347 A	24-10-2000		A200021 A1	22 67 1000
U3 013034/ A	24-10-2000	DE US	4200821 A1	22-07-1993
		AT	5695784 A 186212 T	09-12-1997
	•	AU	670763 B2	15-11-1999 01-08-1996
	,	AU	3113893 A	22-07-1993
		CA	2087146 A1	16-07-1993
		CN	1074603 A ,B	28-07-1993
		CZ	9203720 A3	11-08-1993
		DE	59309858 D1	09-12-1999
		DK	551820 T3	25-04-2000
		ΕP	0551820 A1	21-07-1993
		ĒS	2141117 T3	16-03-2000
		GR	3032382 T3	27-04-2000
		HK	1005987 A1	12-05-2000
		HU	64693 A2	28-02-1994
		HU	211154 B3	30-10-1995
		IL	104362 A	15-04-1997
		JP	5255072 A	05-10-1993



PCT	/IB	03/0	5877

ſ	<del></del>		<del></del>		<del></del>
	Patent document cited in search report	Publication date		Patent family member(s)	Publication date
1	US 6136347 /	1	MX	9207630 A1	30-07-1993
Ì		•	NZ	245658 A	24-02-1995
1			PL	297399 A1	09-08-1993
1			RŪ	2110255 C1	
l			SK		10-05-1998
ı			ZA	372092 A3	10-05-1995
۱				9300234 A	16-08-1993
	US 6106861 #	22-08-2000	FR	2766089 A1	22-01-1999
1			ΑT	208616 T	15-11-2001
١			AU	708197 B2	29-07-1999
ı			AU	4930197 A	04-02-1999
ı	•		AU	8865998 A	16-02-1999
ı			BR	9811803 A	19-09-2000
l			CA	2296710 A1	04-02-1999
ł			CN	1264299 T	23-08-2000
ı			DE	69802543 D1	20-12-2001
ı			DE	69802543 T2	22-08-2002
١	•		DK	1003484 T3	25-02-2002
ı			EP	0896818 A1	17-02-1999
ı			EP	1003484 A1	31-05-2000
l			ES	2167921 T3	16-05-2002
ı			WO	9904763 A1	04-02-1999
ı			HU	0003691 A2	28-04-2001
ĺ			JP	3190299 B2	23-07-2001
1			JP	11035450 A	09-02-1999
ı			NZ	502228 A	29-06-2001
			PT	1003484 T	31-05-2002
ĺ			SI	20059 A	30-04-2000
ĺ			TR	200000139 T2	21-09-2000